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Pharmacy Compliance – Prioritized Areas of Focus

Prioritization methodology

In collaborating with Corporate Pharmacy managers, we have identified areas of focus for Pharmacy Compliance and Regulatory Affairs. Prioritization is based on the need to

- re-evaluate compliance processes, procedures and controls to improve effectiveness or efficiency of execution
- minimize the potential for gaps or inconsistencies due to de-centralization of responsibility, and
- conduct a thorough review to ensure we are minimizing risk to Publix.

Prioritization is further broken down and assigned an effort level in order to determine how we will align our resources. The state of current regulatory enforcement efforts and regulatory mandated implementation timelines are also considered.

Top priorities

The prioritized work is listed in the chart below reflecting the priority and expected level of effort to accomplish the objectives.

		(A) Compliance/Training Focus Areas	(B)
Priority	High	<ol style="list-style-type: none"> 1. Evaluate and document billing & overpayment processes/controls 2. Attestation & audit support for MC/Specialty (compliance policies, training & education, and personnel records) 3. Managed Care contract compliance assessment and process improvements 4. Centralized solution for controlled substance significant loss reporting 5. Regulatory monitoring process to ID & coordinate response to laws, rules, comment requests, letters of clarification, etc. 6. Evaluate and document current Controlled Substance handling, dispensing & disposal processes 	<ol style="list-style-type: none"> 1. License monitoring including OIG checks (e.g., associate, facility, key vendor, attestation support) 2. Prescriber license monitoring including OIG checks and prescriptive authority 3. Compound pricing & billing 4. Controlled substance SOM system review & improvements including consideration of the “total” order 5. Controlled substance diversion analytics and associated investigation structure 6. CSOS for warehouse orders 7. FWA/Billing analytics\ 8. State analysis of compliance implications related to health system collaborations (preparation for new business expansion)
	Low	<ol style="list-style-type: none"> 1. CSR 50-state integrity check & ongoing mgmt. 2. PDMP review tool solution (e.g., Opisafe, Appriss) 3. Label requirements evaluation by state 4. Clerk role evaluation and recommendation 5. REMS program structure 6. Recall and Adverse Event reporting 7. Pharmacy App re-education and job aid 8. Evaluate meeting PIC requirements by state 	<ol style="list-style-type: none"> 1. Controlled substance training – red flags/pt care 2. Comprehensive program to meet tech state ratio requirements & tech education/certification requirements 3. Central Pharmacy policy and procedure 4. Advanced billing training 5. Hospital job class training 6. USP 795 & 800 preparation for 12/1/19 compliance deadline (current USP compliance evaluation & response too) 7. DSCSA evaluation & implementation (2018-2023)
		(C) Effort	(D) High

TIME

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